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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,353	06/08/2007	Jay Lal Mehta	056291-5246	8786

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EXAMINER	
BETTON, TIMOTHY E	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,353	MEHTA, JAY LAL	
	Examiner	Art Unit	
	Timothy E. Betton	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 12-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 12-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 12-16, drawn to a combination comprising candesartan or a pharmaceutically acceptable salt thereof and rosuvastatin or a pharmaceutically acceptable salt thereof in amounts synergistically effective in the prevention or treatment of atherosclerosis and cardiovascular events in association with a pharmaceutically acceptable diluent or carrier, wherein candesartan is in the form of candesartan cilexetil, classified in class 514 and subclass 263.320.

Group II, claim(s) 17 and 18, drawn to kits comprising: a) candesartan or a pharmaceutically acceptable salt thereof in a first unit dosage form; b) rosuvastatin or a pharmaceutically acceptable salt thereof in a second unit dosage form; and c) container means for containing said first and second dosage forms; and optionally d) instructions for use in the prevention or treatment of atherosclerosis, wherein the candesartan and rosuvastatin are present in said first and second unit dosage forms, respectively, in amounts synergistically effective in the treatment of atherosclerosis classified in class 514 and subclass 263.320.

Group III, claim(s) 19-26, drawn to various method procedures drawn to the administration of candesartan or a pharmaceutically acceptable salt thereof and rosuvastatin or a pharmaceutically acceptable salt thereof, classified in class 514 and subclass 263.320.

The inventions listed as Groups I through III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Otake et al. (USPGPUB 2004/0054177 A1) teach aspects and embodiments of claimed invention which would qualify as prior art. Specifically, in addition to teaching the objective subject matter of claimed invention drawn to prevention and

treatment enumerating rosuvastatin and candesartan among variable other agents indicated for combination formulations. The compositions of the present invention may be used in combination with other drugs that may also be useful in the treatment, prevention or control of disorders, such as hypertension, hypertension associated with obesity, hypertension-related disorders, cardiac hypertrophy, left ventricular hypertrophy, and metabolic syndrome, obesity and obesity-related disorders, for which compounds comprising the compositions are useful. Such other drugs may be administered, by a route and in an amount commonly used therefore, contemporaneously or sequentially with a composition of the present invention. When a composition of the present invention is used **contemporaneously with one or more other drugs**, a pharmaceutical composition in **unit dosage form containing such other drugs** and the composition of the present invention is preferred. However, the combination therapy also includes therapies in which the composition of the present invention and one or more other drugs are administered on different overlapping schedules. It is also contemplated that when used in combination with one or more other active ingredients, the composition of the present invention and the other active ingredients may be used in lower doses than when each is used singly. Accordingly, the pharmaceutical compositions of the present invention include those that contain one or more other active ingredients, in addition to a composition of the present invention [0030], [0352], [0407], [0420], [0423]. Based on the disclosure above, the term unit is explained in the context of a combination unit of drugs, which could equally be perceivable or broadly interpreted as the basic constitution of a kit-type structure if not directly definable as a kit.

Accordingly, the claimed combination of agents cannot be considered the unifying feature of the inventions of Groups I-III because it fails to demonstrate a contribution over what was already known in the prior art at the time of the invention.

Election of Species Requirement

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT 13.1.

Election of Invention I require Applicant to make the following specie elections:

(i) Election of a single disclosed specie of a specific condition to be treated from those claimed within instant claims 12-16 or a single disclosed specie of a specific condition not directly claimed but which is embodied within instant claims 12-16. For example, applicant must elect; and

(ii) Election of a single disclosed method specie disclosed in instant claims 19-26.

In the event that Applicant should choose a genus to satisfy any of the required elections, then Applicant must further elect a single disclosed specie of condition and/or compound (depending upon the election) within the genus.

Within the method species (claims 19-26), applicant must elect either (1) a method of preventing or treating atherosclerosis, (2) a method of preventing cardiovascular events, (3) a method of preventing or treating an inflammatory disease or condition, (4) a method of inhibiting expression of (i) CD40 or (ii) metalloproteinases (MMPs) or (iii) LOX-1, or (5) a method of treating atherosclerosis. Applicant must elect one specific and exact component for inhibition,

e.g., *a method of inhibiting expression of LOX-1*. In the occasion that applicant elects (3) which is drawn to inflammatory diseases and conditions, applicant must elect a condition selected from ischemia reperfusion injury to (a) heart, b) kidneys, (c) lungs or (d) liver, (e) radiation- induced injury, (f) burn injury and (g) peripheral vascular disease. Further, in the method species, the species drawn to inhibiting expression

For instance, if applicant elects a method species for examination on the merits, a proper election must set forth a species of method that falls within the disclosed genus, such as, e.g., a method for preventing, a method for treating, a method for inhibiting expression, etc. Election of a genus without setting forth a single, specific specie within the genus will be held non-responsive.

The following claims are generic: claims 12-26.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please see MPEP §809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

In view of the species of a pharmaceutical combination/composition the species of disease the said pharmaceutical combination/composition is indicated to prevent and/or treat are distinct diseases and/or disorders via etiology, pathophysiological manifestations, treatment protocols, and patient population such that a comprehensive search for the claimed combination in amounts synergistically effective, for example, atherosclerosis, would not necessarily anticipate or support obviousness over the administration of the same or different combination unit as disclosed in amounts synergistically effective for cardiovascular events.

Accordingly, a comprehensive search of the patent and non-patent literature for atherosclerosis would not necessarily result in a comprehensive search for cardiovascular events. Furthermore, the known complexity of the conditions of cardiovascular events and atherosclerosis is further evidence that a comprehensive search for a particular agent to treat one of such disorders would not necessarily anticipate or render obvious the use of the same for the other disorder. Notwithstanding that Applicant may have established an underlying commonality to the claimed conditions, namely that each may be treated via the claimed combination comprising candesartan and rosuvastatin synergistically effective in treatment for both said conditions *supra.* Furthermore, it remains that the art does not necessarily recognize such a shared characteristic as being common to the entire genus of conditions encompassed by the instant claims, nor does the art necessarily recognize each as amenable to the same type of pharmacologic therapy. Each is considered independent or distinct from the others because the patient populations, dosage amounts and therapeutic protocol for treating each single condition are each unique to the type of disorder being treated such that a comprehensive search for the claimed compound in an amount effective for the treatment of a particular disease in the prior art

would not necessarily encompass a comprehensive search of the patent or non-patent literature for the claimed compound in an amount effective for the treatment of any one or more other diseases.

Furthermore, the species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical feature. In this regard, applicants' attention is once again drawn to Otake et al. (USPGPUB 2004/0054177 A1), which teach aspects and embodiments of claimed invention, which would qualify as prior art. Specifically, in addition to teaching the objective subject matter of claimed invention drawn to prevention and treatment enumerating rosuvastatin and candesartan among variable other agents indicated for combination formulations. The compositions of the present invention may be used in combination with other drugs that may also be useful in the **treatment, prevention** or control of disorders, such as hypertension, hypertension associated with obesity, hypertension-related disorders, cardiac hypertrophy, left ventricular hypertrophy, and metabolic syndrome, obesity and obesity-related disorders, for which compounds comprising the compositions are useful. Such other drugs may be administered, by a route and in an amount commonly used therefore, contemporaneously or sequentially with a composition of the present invention. When a composition of the present invention is used **contemporaneously with one or more other drugs**, a pharmaceutical composition in **unit dosage form containing such other drugs** and the composition of the present invention is preferred. However, the combination therapy also includes therapies in which the composition of the present invention and one or more other drugs are administered on different overlapping schedules. It is also contemplated that when used in combination with one

or more other active ingredients, the composition of the present invention and the other active ingredients may be used in lower doses than when each is used singly. Accordingly, the pharmaceutical compositions of the present invention include those that contain one or more other active ingredients, in addition to a composition of the present invention [0030], [0352], [0407], [0420], [0423]. Accordingly, the claimed combination of agents cannot be considered the unifying feature of the inventions of Groups I-IV because it fails to demonstrate a contribution over what was already established in the prior art at tile time of the invention.

In view of a specie of method procedure drawn to instant claims 19-26, a method of preventing is distinct from a method of treating in the context of intended outcome. Accordingly, a method for inhibiting would not necessarily be interpreted as a method of treating and/or preventing.

Accordingly, a comprehensive search of the patent and non-patent literature for methods of preventing in the scope of claimed invention would not necessarily result in a comprehensive search for a method of inhibiting expression in the scope of claimed invention and vice-versa. Similarly, methods for treating in the scope of claimed invention would not necessarily result in a comprehensive search for a method of inhibiting expression in the scope of claimed invention and vice-versa. Thus, the claimed combination of agents cannot be considered the unifying feature of the inventions of Groups I-III because it fails to demonstrate a contribution over what was already established in the prior art at tile time of the invention.

Applicant is required, in reply to this action, to elect and invention and species in accordance with tile instruction provided supra to which the claims shall be restricted if no

generic claim is finally held to be allowable. A proper reply to this requirement is required to include an identification of each species that is elected consonant with this requirement readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.
Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.
The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ardin H Marschel 11/10/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER